NONIN®

Operator's Manual

Avant® 4100

Avant® 4100

Avant® 4000 Digital Pulse Oximetry System with Bluetooth® Wireless Technology

CE 0123

English

CAUTION! Federal law (USA) restricts this device to sale by or on the order of a physician.

CAUTION! Read this entire manual carefully before using the Avant 4000 Digital Pulse Oximetry System.

The information in this manual has been checked carefully and is believed to be accurate. In the interest of continued product development, NONIN reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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Guide to Symbols

Detailed information for functional symbols can be found in "Using the Avant 4000 Digital Pulse Oximetry System."

Regulatory Symbols

Attention: See Instructions for Use or related materials.

Type BF Applied Part
(Patient isolation from electrical shock).

UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1.

CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.

SN

Serial Number (located under the back cover).

Indicates separate collection for electrical and electronic equipment (WEEE).

Non-ionizing electromagnetic radiation. Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.

Precautions for Use

Contraindications

Do not use any part of this system in an MRI environment.

Explosion Hazard: Do not use this system in an explosive atmosphere or in the presence of flammable anesthetics or gases.

Warnings

This system is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Oximeter readings may be affected by the use of an electrosurgical unit (ESU).

Use only NONIN-manufactured PureLight™ sensors. These sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

Do not use a damaged sensor.

Do not use in or around water or any other liquid when the AC power adapter is used.

Use this pulse oximetry system with 300PS-XX AC power adapters, where XX represents the power supply designation.

As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.

All parts and accessories connected to the serial port of this system must be certified according to IEC Standard EN 60950 or UL 1950 for data-processing equipment.

To avoid the risk of confusing or misinterpreting patient data, verify that the Model 4100 wrist-worn patient module is paired with the correct display unit.

This pulse oximetry system is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.

The battery pack must be installed at all times while the device is operating—even when operating on AC power. If it is necessary to operate the device without batteries, audible alarms and memory functions may not be available. DO NOT use the device without batteries when patient safety relies upon audible alarms.

Use the Avant 4000 system only within its designated range (approximately 30 feet—spherical radius—from patient module to display). Moving outside this range may cause missing, lost, and/or inaccurate data.

Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.

This system may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributor's contact information.

The use of accessories, sensors, and cables other than those listed in this manual may result in increased emission and/or decreased immunity of this device.

Cautions

This equipment complies with International Standard EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.

Portable and mobile RF communications equipment can affect medical electrical equipment.

If this pulse oximetry system fails to respond as described, discontinue use until the situation is corrected by qualified personnel.

Cardiogreen and other intravascular dyes may affect the accuracy of SpO_2 measurements.

The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.

This system might misinterpret motion as good pulse quality. Minimize finger motion.

Some nail polish colors or artificial nails can reduce light transmission and affect SpO_2 accuracy.

Before using any sensor, carefully read the Directions for Use, which contain specific application information for each sensor.

Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition.

Do not place liquids on top of this pulse oximetry system.

Do not immerse the pulse oximetry system or sensors in any liquids.

Do not use caustic or abrasive cleaning agents on the unit or sensors.

Do not gas sterilize or autoclave this pulse oximetry system.

Batteries might leak or explode if used or disposed of improperly.

Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Use only NONIN-approved battery packs, and remove batteries if the system is not used within 30 days.

When using the 300PS-UNIV battery charger, ensure that the AC cord is plugged into a grounded outlet.

Do not fasten the patient module too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.

Caution: Exposure to Radio Frequency Radiation. The radiated output power of the display unit is far below FCC radio frequency exposure limits. Nevertheless, the device must be used in such a way that the potential for human contact during normal operation is minimized. To avoid the possibility of exceeding FCC radio frequency exposure limits, remain at least 20cm (8 inches) away from the display unit's internal antenna during normal operation. The wrist-worn patient module has been tested and meets allowed limits for exposure.

This device has not been tested for immunity to electromagnetic disturbances.

Verify all alarm settings during system startup to ensure that they are set as intended.

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 2605 Fernbrook Lane North, Plymouth, Minnesota, 55447, declares under its sole responsibility that the Models 4000 and 4100, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures: (1) Reorient or relocate the receiving antenna, (2) Increase the distance between the equipment and the receiver, (3) Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected, or (4) Consult the dealer or an experienced radio/TV technician for assistance.

The Model 4100 wrist-worn patient module is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-200X (Draft 6.5, January 2002).

RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components and provide a separation distance of 15mm (0.6 inches) to the body. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

NOTE:No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

Manufacturer's Declaration

Refer to the following table for specific information regarding this device's compliance to IEC Standard 60601-1-2.

Table 1: Electromagnetic Emissions

Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

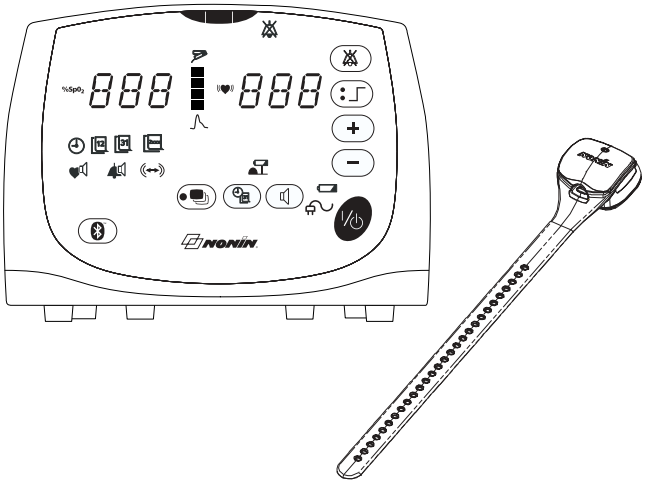
Using the Avant® 4000 Digital Pulse Oximetry System

This chapter describes how to use the Avant® 4000 Digital Pulse Oximetry System. The system includes the following components:

- Avant 4000 display unit with rechargeable battery pack
- Avant 4100 Wrist-Worn Patient Module with AA batteries
- 8000AA-WO finger-clip sensor
- Operator's manual
- Universal Desktop Battery Charger with IEC320 Connector
- 3 wrist bands

Indications for Use

The NONIN® Avant® 4000 Digital Pulse Oximetry System is indicated for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, and infant patients. It is indicated for spot checking and/or continuous monitoring.

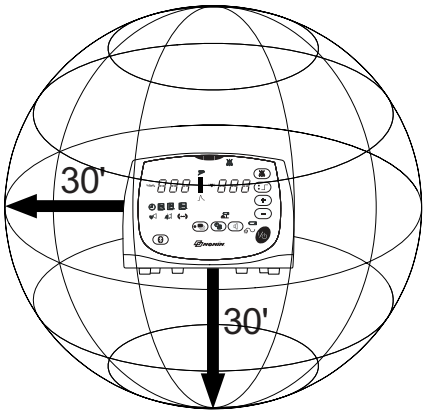


The Avant 4000 Digital Pulse Oximetry System: Display Unit and Patient Module.

General Information about Bluetooth Technology

Bluetooth is a technology that enables automatic wireless connections between a variety of electronic communications and computing devices, making it possible to connect any compatible devices without cables or wires. The technology is based on a radio link that offers fast and reliable transmissions of voice, video, and data. Bluetooth uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

Nonin's use of Bluetooth Wireless Technology allows SpO_2, pulse rate, and plethysmographic data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's system removes the connection from the sensor cable to the display unit, giving patients increased ability to move freely—without being hindered by cables. Nonin's patient module uses a class II Bluetooth radio with a battery life of about 120 hours and a range of about 30 feet (spherical radius). The display unit has a minimum operating battery life of 18 hours.

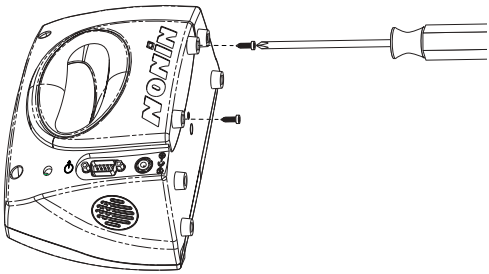


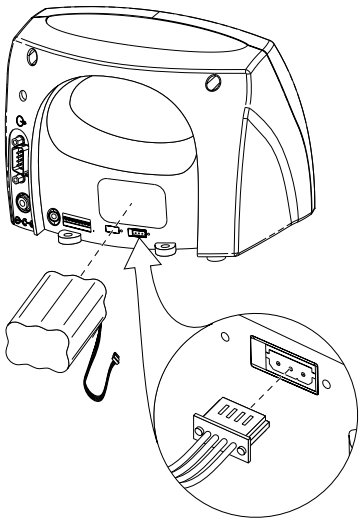
Point-to-Point Communications

The Avant 4000 System features point-to-point communications, allowing one master device (the display unit) to be paired to one slave device (the patient module). Once connected, neither device is detectable by any other Bluetooth-enabled device, which reduces the risk of interference and preserves data integrity.

Installing the Battery Pack in the Display Unit

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. If it is necessary to operate the device without batteries, audible alarms and memory functions may not be available. DO NOT use the device without batteries when patient safety relies upon audible alarms.

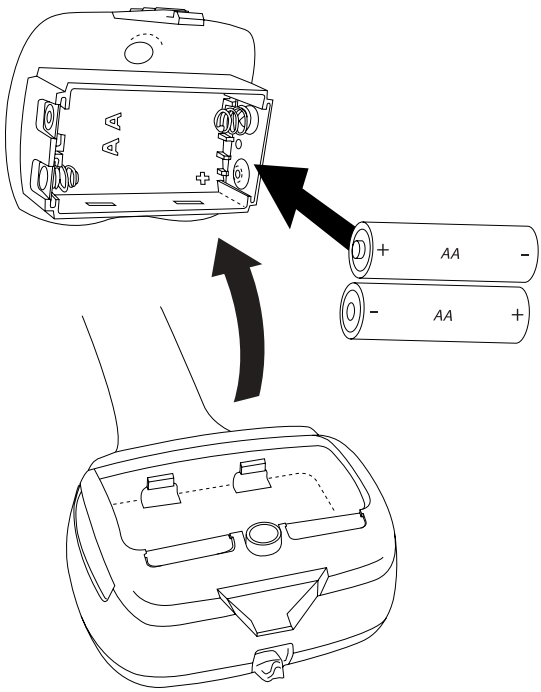


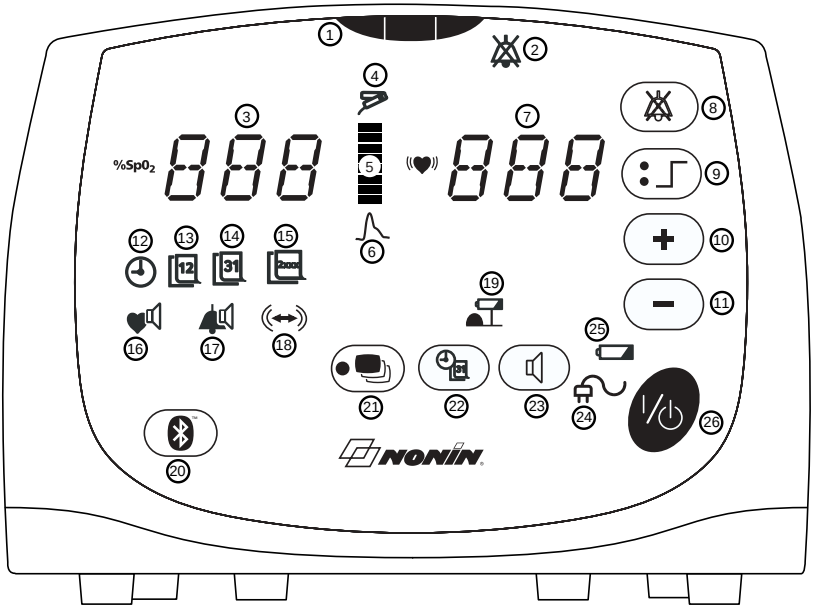


NOTE: Contact your distributor or NONIN to purchase or replace battery packs.

NOTE: Reposition the back cover carefully, and tighten the screws firmly—being careful not to over-tighten.

Installing Batteries in the Patient Module





1 Main Alarm LED
2 Alarm Silence LED
3 Numeric LEDs for %SpO2 data
4 Pulse Oximeter Sensor LED
5 Pulse Strength Bargraph LED
6 Pulse Quality LED
7 Numeric LEDs for Pulse Rate data
8 Alarm Silence Button
9 Alarm Limits Button and Indicator
10 Plus Button
11 Minus Button
12 Time LED
13 Month LED
14 Day LED
15 Year LED
16 Pulse Volume LED
17 Alarm Volume LED
18 Connection Status LED
19 Remote Battery Status LED
20 Bluetooth Control Button
21 Memory Button
22 Time/Date Button
23 Volume Button
24 AC Power Adapter LED
25 Battery LED
26 ON/STANDBY Button

Displays, Indicators, and Controls

This section describes the Avant 4000 System's displays, indicators, and controls.

Parameter Displays

%SpO_2 Display

Numeric light-emitting diodes (LEDs) on the upper left-hand corner of the Avant 4000 display unit display blood oxygen saturation in percent.

Pulse Rate Display

The pulse rate display is located on the upper right-hand corner of the Avant 4000 display unit and is identified by the ((♥)) symbol. This display shows the pulse rate in beats per minute.

Numeric LEDs

Numeric LEDs display %SpO_2 and pulse rate values. When setting the device, these LEDs also display values for alarm limits, volume, year, month, day, hour, and minute displays. They also display device identification numbers and error codes.

Under normal conditions, these LEDs display in green. For high priority (patient) alarms, the corresponding values are displayed in red, blinking fast. The values are displayed in amber for medium priority alarms and when reviewing or changing limits, volumes, date, or time.

Front Panel Buttons

ON/STANDBY Button

Pressing this button once turns on the Avant 4000 display unit. Holding this button for at least 1 second shuts down the display unit. Briefly pressing this button while the unit is on displays the battery charge in 10% increments for 4 seconds in green. This button also controls the device's event marker and print-on-demand features. See this manual's "Communication" section for more information.

Time/Date Button

This button displays the time and date. Year, month, day, hour, and minute can be set using the Plus (+) and Minus (-) buttons.

Volume Button

This button allows users to set and review the pulse or alarm volume, depending upon which corresponding LED is illuminated. This button cycles users between alarm volume and pulse volume.

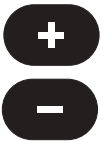
Alarm Silence Button

This button toggles the alarm between silenced and audible. Pressing the Alarm Silence button will silence the alarm for two minutes.

Alarm Limits Button and Indicator

This button displays the upper and lower limits for alarm indications for SpO_2 and heart rate measurements. These limits can be adjusted using the Plus (+) and Minus (-) buttons. The Alarm Limits button cycles users through the display unit's alarm settings, allowing users to both set and review alarm limits.

The upper LED on the Alarm Limits button indicates the upper alarm limit, and the lower LED indicates the lower alarm limit.



Plus Button and Minus Button

These buttons adjust values for many functions. The Plus and Minus buttons are used to adjust time, date, volume, and upper and lower alarm limits. Pressing either of these buttons alone, when the display unit is not in any setting mode, adjusts the intensity of the LED displays. These buttons are also used to select from multiple wrist-worn patient modules during pairing.

Memory Button

This button is used to enter Memory Playback mode.

Bluetooth Control Button

Press and hold this button while turning on the display unit to begin the device pairing process. A maximum of five "pairable" patient modules may be displayed separately, with the device identification number appearing in the pulse rate and SpO_2 display area. While five devices may be shown, only one may be selected (paired).

Select the patient module you want to pair with by using the Plus or Minus buttons to scroll through the available modules. When the identification number of the patient module you wish to pair with is shown—*and is not flashing*—press the Bluetooth Control button again. When the pairing process is complete, normal operation resumes automatically. After the device is paired to a patient module, it will remain paired until the above process is repeated.

During normal operation, pressing the Bluetooth Control button displays the selected patient module's device identification number for three seconds in the pulse rate and SpO_2 display area. See "Device Pairing" for more information.

Indicators and Icons

Main Alarm LED

This LED indicates all alarm conditions. For high priority (patient) alarms, the indicator is displayed in red, blinking fast. For medium priority alarms, the indicator is displayed in amber, blinking slowly.

Pulse Quality LED

This LED blinks to indicate a poor pulse signal. If there is a sustained period of poor quality signals, this LED will illuminate steadily.

Pulse Oximeter Sensor LED

This LED indicates when a sensor has become disconnected, has failed, or has not been applied correctly.

Pulse Strength Bargraph LED

This 10-segment tricolor bargraph indicates pulse strength as determined by the oximeter. The height of the Pulse Strength Bargraph LED is proportional to the pulse signal, and the color is determined by pulse strength:

Green = a good pulse strength
Amber = a marginal pulse strength
Red = a low pulse strength, high priority alarm

When displaying battery charge, this LED indicates charge in 10% increments in green, displaying the depleted portion in amber.

Alarm Silence LED

This amber LED indicates that the audible alarm is silenced for two minutes when it blinks. When lit steadily, the Alarm Silence LED indicates that the audible alarm volume is set to zero.

Time, Month, Day, and Year LEDs

These amber LEDs indicate that the display unit's *Time*, *Month*, *Day*, or *Year* displays can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Pulse Volume LED

This amber LED indicates that the Pulse Volume can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Alarm Volume LED

This amber LED indicates that the Alarm Volume can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Connection Status LED

This LED is lit green when a patient module is connected with the display unit. It is lit amber when no devices are connected, and it blinks during device pairing. The Connection Status LED works in sync with the patient module's connection status indicator.

Remote Battery Status LED

This amber LED alerts users to marginal or critical battery conditions for the wrist-worn patient module. When the patient module's batteries are marginal, this LED blinks. When battery capacity is critical, it remains lit steadily.

AC Power Adapter LED

This green LED is displayed when an external power supply is providing power to the display unit.

Battery LED

This amber LED indicates a marginal battery charge when blinking. In addition, this LED—when lit steadily—indicates that the battery charge is being displayed**.** *This LED does not indicate that the display unit is running on battery power.* The battery charge indication will not be accurate before one full charge/discharge/recharge cycle with a new battery pack.

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. If it is necessary to operate the device without batteries, audible alarms and memory functions may not be available. DO NOT use the device without batteries when patient safety relies upon audible alarms.

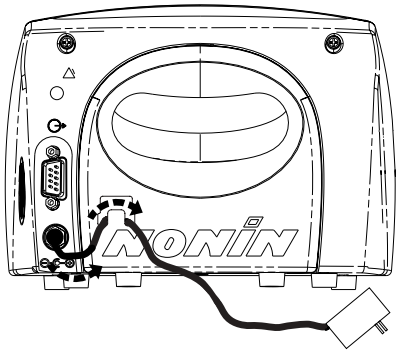
Setting Up the Avant 4000 Digital Pulse Oximetry System

Use the following procedure to set up the Avant 4000 Digital Pulse Oximetry System. (Refer to the Avant 4100 Patient Module instruction insert for additional information about using that product.)

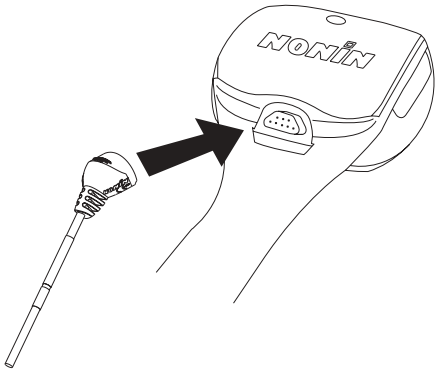
1. Ensure that batteries are installed in the display unit and wrist-worn patient module.

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. If it is necessary to operate the device without batteries, audible alarms and memory functions may not be available. DO NOT use the device without batteries when patient safety relies upon audible alarms.

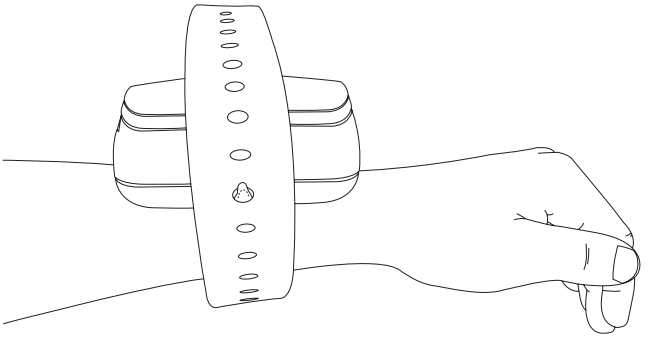
2. Plug in and connect the AC adapter for the display unit.

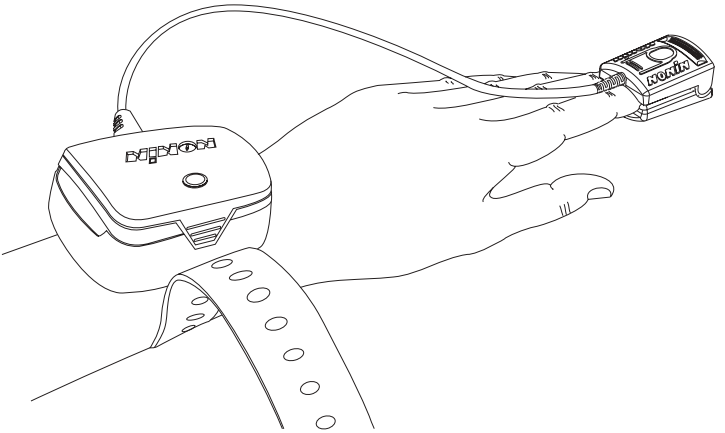


3. Attach a sensor to the patient module. (The patient module is automatically activated when a sensor is connected.)



4. Press the ON/STANDBY button to turn on the display unit.
5. Verify operation of the display unit, and pair the display unit with the desired wrist-worn patient module. (See "Verifying System Operation" and "Device Pairing" for more information.
6. Secure the wristband to the patient's wrist.





NOTE: If desired, any excess strap material may be trimmed and discarded.

Verifying System Operation

When the display unit is first turned on, it performs a brief startup (initialization) sequence. Verify that all LEDs illuminate and the unit beeps three times during the first phase of the startup sequence. If any LED is not lit (except the AC Power Adapter LED), do not use the device. Contact your distributor or NONIN Customer Support for assistance.

After this initialization sequence, the amber Connection Status LED and amber dashes are displayed, turning green when communication is established and a Bluetooth connection is made (devices must be paired before a Bluetooth connection can be established; see "Device Pairing" on the next page). The Main Alarm LED and Pulse Oximeter LED blink amber until the oximeter produces valid readings.

CAUTION: Verify all alarm settings during system startup to ensure that they are set as intended.

Use the procedure below to monitor SpO_2 and pulse rate readings in order to verify that the device is functioning properly.

1. Ensure that the display unit is turned on, and that the unit has been paired with the desired wrist-worn patient module. (See "Device Pairing" for more information.)
2. Connect a sensor to the patient module, pressing firmly to make sure it is securely connected.
3. Apply the patient module around the wrist, and attach the sensor to the patient's finger. Connecting the sensor automatically activates the patient module; there are no buttons to press.
4. Verify that the Connection Status LEDs on both the display unit and the patient module are green.
5. Verify that a good SpO_2 reading is displayed, that a pulse rate value appears, and that the Pulse Strength Bargraph LED is active.

Device Pairing

Use the following procedure to pair the display unit with a desired wrist-worn patient module.

NOTE: To ensure proper pairing, disconnect and then reconnect the sensor from the patient module before beginning.

NOTE: The Avant 4000 display unit must be OFF before pairing devices.

1. Press and hold the Bluetooth Control button while turning on the display unit to begin the device pairing process. Notice that amber dashes flash in the SpO_2 and Pulse Rate display areas as the system searches for patient modules available for pairing. (If a patient module is available, its identification number will appear on the display unit screen within 10 seconds.)
2. When available patient module(s) are detected, a maximum of five "pairable" patient modules will be displayed separately, with the device identification number appearing in the SpO_2 and Pulse Rate display areas. (A unique device identification number is included on the sides of each patient module.)
3. If multiple patient modules are available for pairing, use the Plus or Minus buttons to scroll through the available modules. (While five devices may be available, only one may be selected for pairing.)
4. When the identification number of the patient module you wish to pair with is shown—*and is not flashing*—press the Bluetooth Control button again to complete the pairing process. Normal operation resumes automatically when the pairing process is complete.
5. To confirm that the pairing process was successful, ensure that the Connection Status LED is lit green.

NOTE: After the display unit is paired to a patient module, it will remain paired until the above process is repeated.

Default Settings

The Avant 4000 display unit features Factory Default and User-Defined Default settings.

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. If it is necessary to operate the device without batteries, audible alarms and memory functions may not be available. DO NOT use the device without batteries when patient safety relies upon audible alarms.

CAUTION: Verify all alarm settings during system startup to ensure that they are set as intended.

Factory Default Setting

In Factory Default setting, all adjustable alarm and volume parameters are set at their default values. Factory Default setting is the system's default operating setting. It is indicated by DIP switch 8 in the DOWN position. For more information about default alarm values, refer to this manual's "Alarms and Limits" section.

NOTE: Any alarm and volume adjustments made while the device is operating in Factory Default Setting will be lost when the device is shut down. The last adjusted values can be recalled by pressing and holding both the Alarm Limits and ON/STANDBY buttons when turning on the display unit.

User-Defined Default Setting

In User-Defined Default Setting (DIP switch 8 in the UP position), alarm limit settings must be adjusted. When this setting is first activated, valid limit settings must be entered for SpO_2 and pulse rate alarm limits; the system will not return to normal operating mode until all limits have been set. Once set, the adjusted values are used as defaults until the system is turned on with DIP switch 8 in the DOWN position, at which time the device restarts in Factory Default setting.

NOTE: In order to initiate User-Defined Defaults, the unit must be turned on with DIP switch 8 in the UP position.

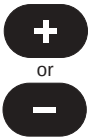
NOTE: Once User-Defined Default Settings are entered, any alarm and volume adjustments made while operating the device will be lost when the device is shut down.

Accessing User Functions

This system includes Basic, Set, and Advanced Functions.

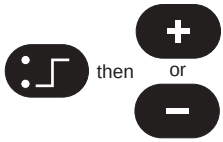
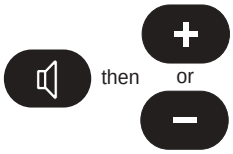
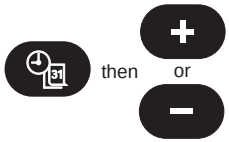
Basic Functions

Basic functions are generally easy to use and involve only a single button. The Avant 4000 display unit has several basic functions.

Function	*Button*	*Instruction*
Turn the display unit on and off.		Press the ON/STANDBY button to turn on the display unit. Press and hold the button for at least one second to turn off the display unit.
Check the battery charge.		Press the ON/STANDBY button while the unit is on. Battery charge is displayed (in 10% increments, for 4 seconds in green) on the Pulse Strength Bargraph.
Mute the audible alarms (2 minutes—toggle).		Press the Alarm Silence button.
Adjust the display intensity (brightness).		Press the Plus or Minus button.
View the patient module identification number currently in use.		Press the Bluetooth Control button during normal operation.
Invoke the print-on-demand feature.		With DIP switch 4 in the DOWN position, press the ON/STANDBY button.
Invoke the event marker.		Press the ON/STANDBY button during real-time printing.

Set Functions

Set functions are those that require multiple buttons to alter a measurement or device parameter for normal operation.

Function	*Button*	*Instruction*
Set alarm limits.		Press the Alarm Limits button to step through the Limits menu. Use the Plus or Minus buttons to adjust alarm limits.
Set pulse and alarm volumes.		Press the Volume button to select pulse or alarm volume. Use the Plus or Minus buttons to adjust the selected volume.
Set time and date.		Press the Time/Date button to step through the Time/Date menu. Use the Plus or Minus buttons to adjust the time and date values.

Advanced Functions

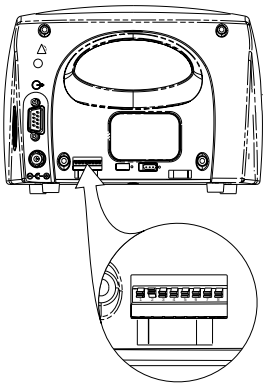
Advanced functions are restricted to trained users; they require multiple button presses in order to prevent accidental activation.

Function	*Button*	*Instruction*
Pair Devices		Press and hold the Bluetooth Control button while turning on the display unit. A maximum of five "pairable" patient modules will be displayed, with the device identification number appearing in the pulse rate and SpO_2 display areas. When the desired patient module's identification number is displayed, pressing the Bluetooth Control button completes the pairing process.
Retain Previous User-Defined Alarm Limit Settings		Press and hold both the Alarm Limits and ON/STANDBY buttons when turning on the display unit.
Enter Patient Playback and Memory Clear Menu		Press and hold the Memory button while turning on the display unit. This menu functions with NONIN's nVISION® software.

Display Unit DIP switches

The Avant 4000 display unit contains eight DIP switches that are located behind the back cover of the unit. The UP position is toward the top of the unit, and the DOWN position is toward the bottom of the unit. *The factory setting for all DIP switches is the DOWN position.*

Switch	Function
Switch 1	*Reserved for Future Use*
Switch 2	*Alarm Disable Lock* **Up**—Alarm volume may be disabled **Down**—Alarm volume cannot be disabled
Switch 3	*Date Format* **Up**—International Date format (Day-Month-Year) **Down**—U.S.A. Date format (Month-Day-Year)
Switch 4	*Data Output* **Up**—Real-time (once per second) data output **Down**—Print on demand
Switch 5	*Normal / Fast Responding SpO_2 Output* **Up**—Fast responding SpO_2 serial output **Down**—Normal SpO_2 serial output
Switch 6	*Normal / Slow SpO_2 and Pulse Rate Averaging* **Up**—Slow Averaging (8 beat exponential average) **Down**—Normal Averaging (4 beat exponential average)
Switch 7	*Nurse Call Output* **Up**—Continuous **Down**—Momentary
Switch 8	*Factory / User-Defined Defaults* **Up**—User-Defined Defaults for Alarm Limits and Volume Settings **Down**—Factory Defaults for Alarm Limits and Volume Settings

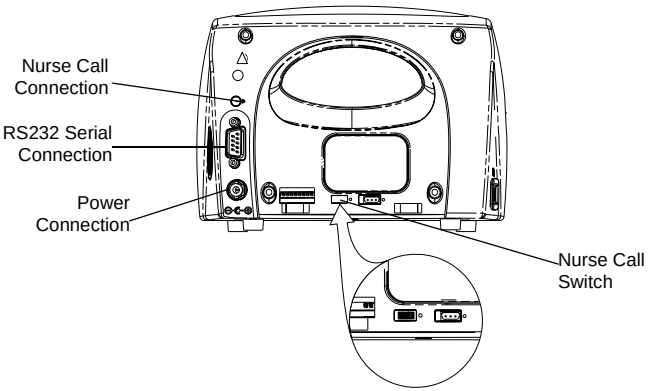


Nurse Call Feature

The Avant 4000 features a Nurse Call circuit that can be connected to a hospital nurse call system, allowing alarm conditions to be recognized at a central monitoring location and on the Avant 4000.

DIP switch 7 allows users to select the duration output of a signal. In the DOWN position, a one-second signal is output when an audible alarm starts. In the UP position, the nurse call signal is active during the entire duration of an audible alarm.

Included in the Nurse Call Circuit is a switch—located on the base of the back panel and covered by the back cover to prevent accidental toggling—that allows users to select NO (Normally Open—the left position) or NC (Normally Closed—the right position). (See "Installing the Batteries" for instructions on removing the back cover.) The Nurse Call Circuit can be used both when the Avant 4000 is plugged in and when it is running on battery power.



Relay Channel Selected	Normal Operation	Alarm Condition	Off
Normally Open (NO)	Open	Closed	Open
Normally Closed (NC)	Closed	Open	Closed

WARNING: It is the user's responsibility to implement the interface between the Nurse Call system and the Avant 4000, and to adequately test the interface between the 4000 and the Nurse Call system to ensure that the desired function is operational.

Care and Maintenance

The advanced digital circuitry within the pulse oximeter of this system requires no calibration or periodic maintenance other than battery replacement.

Field repair of system circuitry is not possible. Do not attempt to open the case or repair the electronics. Opening the case will damage the unit and void the warranty. If the system is not functioning properly, see "Troubleshooting."

Cleaning the Avant 4000 Digital Pulse Oximetry System

Clean all system components with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto components, and do not allow any liquids to enter any openings in the device. Allow the unit to dry thoroughly before reuse.

IMPORTANT! Do not immerse the device in liquid, and do not use caustic or abrasive cleaning agents on the device.

Clean the device separately from its associated sensors. For instructions regarding cleaning pulse oximeter sensors, refer to the appropriate pulse oximeter sensor package inserts.

Alarms and Limits

This chapter describes alarms and limits for the Avant 4000 Digital Pulse Oximetry System.

Alarms and Informational Tones

The Avant 4000 display unit provides high and medium priority audible and visual alarms, as well as informational tones.

High Priority Alarms

High priority alarms are those that require immediate attention to the patient. They include SpO_2, pulse rate, and low perfusion alarms. On the display unit, high priority alarms are indicated with rapidly blinking red LED displays when alarm limits are met or exceeded. In addition, the pulse strength bargraph LED may illuminate a red segment to indicate low perfusion.

High priority alarms are sounded as follows: “beep, beep, beep,” (short pause), “beep, beep” (10-second pause).

Medium Priority Alarms

Medium priority alarms are those that signal potential problems with the equipment or other non-life-threatening situations. On the display unit, medium priority alarms are indicated with slowly blinking amber displays.

Medium priority alarms are illuminated amber on the Main Alarm LED and on the appropriate indicator(s) or numeric displays, sometimes displaying an error code to help the user identify the source of the error.

Medium priority alarms are sounded as follows: “beep, beep, beep,” (25-second pause), “beep, beep, beep.”

Informational Tones

Informational tones communicate important information. They are typically single “beeps” or a series of three “beeps.” Informational tones include the startup/initialization tone and the pulse rate tone (which changes in pitch with SpO_2 values).

Alarm Summary

If patient SpO_2 or pulse readings are equal to or above the upper alarm limit, or if they are equal to or below the lower alarm limit, the display unit will signal an alarm.

High Priority Alarm Description	*Factory Default*	*Adjustment Range*	*Step Value*
SpO_2 Upper Alarm Limit	Off	Off, 80 to 100	1% SpO_2
SpO_2 Lower Alarm Limit	80%	Off, 50 to 95	1% SpO_2
Pulse Upper Alarm Limit	200 BPM	Off, 75 to 275	5 BPM
Pulse Lower Alarm Limit	50 BPM	Off, 30 to 110	5 BPM

Silencing Alarms

Momentary (2-Minute) Alarm Silence

To silence alarms for two minutes, press the Alarm Silence button.

Continuous Alarm Silence

In order to permanently silence all alarms, DIP switch 2 must be placed in the UP position. This allows the alarm volume to be set to zero. *The Alarm Silence LED will remain illuminated when the alarm volume is set to zero.* Refer to "DIP Switches" for more information.

Adjusting Volume and Alarm Limits

Follow the instructions below to review, set, or adjust volumes and alarm limits while operating the Avant 4000 System. **Do not use these instructions to store adjusted limits.** For more information about permanently storing adjusted settings, refer to "Default Settings."

CAUTION: Alarm limits reset themselves to default values each time the unit is powered up. Verify all alarm settings during system startup to ensure that they are set as intended.

Reviewing, Setting, or Adjusting SpO_2 and/or Pulse Alarm Limits

1. Ensure that the display unit is on.
2. Press the Alarm Limits button.
   - Notice that the upper round LED is illuminated to the left of the Alarm Limits button. This indicates the upper alarm limit, while the lower LED indicates the lower alarm limit.
   - Notice that the current setting appears in the $\%SpO_2$ display.
   - Continue to press the Alarm Limits button until the alarm limit you want to adjust is displayed.
   - The Alarm Limits button can also be cycled to exit Set/Change mode, or Set/Change mode will exit automatically after ten seconds with no activity.
3. Ensure that the appropriate upper or lower Alarm Limit LED is illuminated, and that the alarm limit you want to change is displayed.
4. Press the Plus (+) or Minus (-) buttons to adjust the values as desired. Once adjusted, Set/Change mode will exit automatically after ten seconds with no activity, and the new limits will be active.

Reviewing, Setting, or Adjusting Pulse and/or Alarm Volumes

1. Ensure that the display unit is on.
2. Press the Volume button once to change the alarm volume, or twice to change the pulse volume.
   - After pressing the Volume button once, notice that the Alarm Volume LED appears, and the current setting appears in the Pulse Rate display area.
   - After pressing the Volume button twice, notice that the Pulse Volume LED appears, and the current setting appears in the Pulse Rate display area.
   - The Volume button can also be cycled to exit Set/Change mode, or Set/Change mode will exit automatically after ten seconds with no activity.
3. Use the Plus (+) or Minus (-) buttons to adjust the alarm or pulse volumes as desired. Once adjusted, Set/Change mode will exit automatically after ten seconds with no activity, and the new limits will be active.

Error Codes

The Avant 4000 display unit includes error codes that indicate problems with the unit. To correct error conditions, perform the following steps:

1. Turn the unit off and then back on again to remove the error code.
2. If the error persists, disconnect all power (AC and battery), and then reconnect the power and turn the unit back on.
3. If the error still persists, note the error code and contact your distributor, or contact Nonin Customer Support at (800) 356-8874 (USA and Canada) or +1 (763) 553-9968.

Communication

This chapter describes the memory, printing, and real-time capabilities of the Avant 4000 Digital Pulse Oximetry System.

Memory Features

The display unit can collect and store up to 33.5 hours of SpO_2 and pulse rate information.

Data may be played back with data retrieval software (NONIN's nVISION® software is recommended). If you wish to create your own software, contact NONIN for the data format.

NOTE: Only SpO_2 and pulse rate data are available for data retrieval.

The memory in the system functions much like an "endless loop" tape. When the memory fills up, the unit begins overwriting the oldest data with the new data.

Each time the system is turned on, the current time/date information (if the clock is set properly) is stored in memory, starting a new recording session. (See "Displays, Indicators, and Controls" for more information about setting the clock.) Only recording sessions greater than one minute in length are stored in memory.

Patient SpO_2 and pulse rate are sampled every 2 seconds. The extreme value is stored every 4 seconds. Oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

The stored pulse rate ranges from 18 to 300 pulses per minute. The stored values are in increments of one pulse per minute in the interval from 18 to 200, and in increments of two pulses per minute in the interval from 201 to 300.

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. If it is necessary to operate the device without batteries, audible alarms and memory functions may not be available. DO NOT use the device without batteries when patient safety relies upon audible alarms.

Playing Back Memory Data

The Avant 4000 Digital Pulse Oximetry System has a Memory Playback feature, allowing stored data to be output through the RS232 serial connection.

1. With the display unit off, connect the RS-232 connector port of the display unit to the back of your computer using a null modem cable.
2. With the display unit still off, press and hold the Memory button while pressing the ON/STANDBY button.
    - All LEDs will illuminate briefly. PLy bac will appear in the SpO_2 and Pulse Rate LED display areas. This message signals that the device is in Playback mode.
3. The PLy bAC message will disappear when memory playback is complete. (Memory playback may take up to 8 minutes, depending upon the amount of data.) Pressing the ON/STANDBY button will exit Playback mode.
4. A CLr no message will be displayed, and three informational tones will sound.
5. (OPTIONAL): To clear the memory:
    - Use the Plus or Minus buttons to select Clr YES.
    - Press the ON/STANDBY button.
    - To confirm the clearing of memory, use the Plus or Minus buttons to select DEL YES.
    - Press the ON/STANDBY button again.
    - dnE CLr confirms that the memory is clear.
6. Press the ON/STANDBY button to return to normal operation.

Real-Time Patient Data Output

The system provides real-time data output capability via the RS232 connector port. A null modem cable must be connected from the display unit to the receiving computer.

The information from the system in the real-time mode is sent in an ASCII serial format at 9600 baud with 8 data bits, no parity, and 1 stop bit. The data are output at a rate of once per second (on separate lines).

Real-time data may be printed or displayed by devices other than the pulse oximeter. Upon power up, a header is sent identifying the format and the time and date. Thereafter, the data are sent once per second by the system in one of the following formats:

- If DIP switch 8 is in the DOWN position, the data will be displayed as follows:

  SPO2=XXX HR=YYY

  where XXX is the SpO_2 value and YYY is the heart rate value.

- If DIP switch 8 is in the UP position, the data will be displayed as follows:

  SPO2=XXX HR=YYY F

  where XXX and YYY are the fast-responding SpO_2 and pulse rate values.

- If there are no data from the oximeter, the formats will appear as follows:

  SPO2=--- HR=---

Nonin's Avant 4000 Digital Pulse Oximetry System includes an event marker feature. Events are indicated by a single "*****" whenever ON/STANDBY is pressed to enter Battery Capacity Display mode. (ON/STANDBY may be pressed again to exit, or Battery Capacity Display mode will time out after approximately 10 seconds.) This feature can be used to mark exceeded alarm limits, or in other situations as desired.

SPO2=XXX HR=YYY*

Printing Options

The Avant 4000 Digital Pulse Oximetry System features printing capabilities that allow printing on demand or in real-time. These printing options are controlled by DIP switch 4, which is found under the battery cover at the back of the unit.

- When DIP switch 4 is in the UP position, real-time (once per second) data output is available via the RS232 connector port, using a null modem cable.
- When DIP switch 4 is in the DOWN position *(default)*, the Print-on-Demand mode is activated, allowing you to print only when desired.

To print displayed data on demand, press the ON/STANDBY button.

Important Notes

- Event markers are not available in Print-On-Demand mode.
- Print functions are available only with a 9600 baud serial ASCII printer.
- Printing features are not available during memory playback.

Specifications

MODEL 4100 WRIST-WORN PATIENT MODULE	
Oxygen Saturation Range ($\%SpO_2$)	0% to 100%
Pulse Rate Range	18 to 300 pulses per minute
Accuracy	
Blood Oxygen Saturation ($\%SpO_2$) (± 1 S.D.)[a]	70-100% ±2 digits for adults using 8000AA-WO Finger Clip Sensor
	70-100% ±3 digits for adults using 8000J-WO Adult Flex Sensor
Pulse Rate	± 3%
Displays	
Connection Status LED	Amber or green
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 3 mw nominal
Infrared	910 nanometers @ 3 mw nominal
Internal Power	
Battery	Two 1.5 volt AA batteries
Operating Life	minimum 120 hours of continuous operation with new batteries
Storage Life	10 months
Weight	4.4 ounces with batteries (125 grams)
AVANT 4000 DISPLAY UNIT	
Displays	
Numeric Displays	3-digit LEDs, Tricolor (red, green, amber)
Pulse Strength Bargraph LED	Tricolor LED segments
Connection Status LED	Amber or green
Pulse Quality LED	Amber
Power Requirements	
Mains	100-240 VAC 50-60 Hz
DC Input	12 VDC AC adapter
Internal Power	
Battery	7.2 volt battery pack (6 cells)
Operating Life	minimum 18 hours of continuous operation with a fully charged battery pack
Storage Life	17 days
Recharge	4 hours
Dimensions	5.5” H x 7.25” W x 4.5” D

Weight	2.2 lbs with battery
Memory	33.5 hours minimum

AVANT 4000 DIGITAL PULSE OXIMETRY SYSTEM

Temperature	
Operating	32° to +122°F (0° to +50°C)
Storage/Transportation	-22° to +122°F (-30° to +50°C)
Operating Altitude	Up to 40,000 feet
Hyperbaric Pressure	Up to 4 atmospheres
Humidity	
Operating	10% to 90% relative humidity, noncondensing
Storage/Transportation	10% to 95% relative humidity, noncondensing
	*If transferred from a non-operating temperature and/or humidity condition, allow at least one hour of stabilization time before use.
Antenna Type	Inverted F type antenna
Antenna Gain	+2 dB (typ.), +3 dB (max.)

TRANSMITTER

Bluetooth Compliance:	Version 1.1
Operating Frequency:	2.4 to 2.4835 GHz
Output Power:	< 1.1 mW
Operating Range:	10-meter radius indoors
Network Topology:	Point-to-Point
Operation:	Slave: Model 4100; Master: Model 4000
Antenna Type:	Internal
Modulation Type:	Frequency Shift Keying
	Frequency Hopping Spread Spectrum
Band Width	1 MHz

Classifications per *IEC 60601-1; CAN/CSA C22.2 NO.601.1; UL60601-1 30EM*

Type of Protection	Class I (when on AC power with 300PS-UNIV battery charger)
	Internally powered (on battery power)
Degree of Protection	Type BF-Applied Part
Mode of Operation	Continuous

a. S.D. (Standard Deviation) is a statistical measure; up to 32% of the readings may fall outside these limits.

Parts and Accessories

Model Number	Description
AVANTB	Battery Pack
4000 Manual	Operator's Manual for Avant 4000 Digital Pulse Oximetry System
300PS-UNIV	Battery Charger, Universal Desktop w/IEC320 Connector
Contact your distributor or NONIN for options.	Cord Set, Charger
Pulse Oximeter Sensors	
8000AA-WO	Adult Articulated Finger Clip Sensor
8000J-WO	Adult Flex Pulse Oximeter Sensor
8000JFW	Adult FlexiWrap Sensor Wrap
Mounting Accessories	
Pole Mount	Pole Mount
Avant PC	Pole Mount Clamp
Avant RS	Avant Rolling Stand; available in standard or deluxe
Other Accessories	
nVISION®	nVISION® software for Microsoft Windows 95/98/2000/NT 4.0 operating systems
4100WB	Replacement Wrist Bands for Avant 4100 Patient Module (Pkg of 3)
Avant CC	Carrying case for Avant products

For more information about NONIN parts and accessories, contact your distributor, or contact NONIN at (800) 356-8874 (USA and Canada) or +1 (763) 553-9968. This information is also available on NONIN's website: www.nonin.com.

Service, Support, and Warranty

A return authorization number is required before returning any product to NONIN. To obtain this return authorization number, contact NONIN Customer Support:

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, Minnesota 55441-5443 USA

(800) 356-8874 (USA and Canada)
Fax +1 (763) 553-7807
www.nonin.com

+1 (763) 553-9968 (outside USA and Canada)
E-mail: customersupport@nonin.com

Warranty

NONIN MEDICAL, INCORPORATED, (NONIN) warrants to the purchaser, for a period of three years from the date of purchase, each display unit and wrist-worn patient module. NONIN warrants the battery pack for the display unit for a period of one year from the date of purchase.

NONIN shall repair or replace any Avant 4000 Digital Pulse Oximetry System found to be defective in accordance with this warranty, free of charge, for which NONIN has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Avant 4000 Digital Pulse Oximetry System delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from NONIN. All repaired units shall be received by the purchaser at NONIN's place of business. NONIN reserves the right to charge a fee for a warranty repair request on any Avant 4000 Digital Pulse Oximetry System that is found to be within specifications.

This system is a precision electronic instrument and must be repaired by knowledgeable and specially trained NONIN personnel only. Accordingly, any sign or evidence of opening the devices, field service by non-NONIN personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety. All non-warranty work shall be done according to NONIN standard rates and charges in effect at the time of delivery to NONIN.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:
THE EXPRESS WARRANTIES SET FORTH IN THIS MANUAL ARE EXCLUSIVE AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY, SHALL APPLY.

Troubleshooting

Problem	Possible Cause	Possible Solution
The display unit will not activate.	The unit has no power.	Plug in the AC adapter.
The display unit will not operate on batteries.	The battery pack is not connected.	Check the battery pack connection.
	The battery pack is not charged.	Plug in the AC Adapter to charge the battery pack.
	The battery pack is inoperable.	Contact your distributor or NONIN Customer Support for repair or replacement.
You are unable to obtain a green pulse display on the bargraph. *NOTE: In some instances, patient perfusion may be inadequate for pulse detection.*	The patient pulse strength is low or perfused poorly.	Reposition the digit or insert a different digit, and keep the sensor motionless for at least 10 seconds.
		Warm the digit by rubbing or covering with a blanket.
		Position the sensor at a different site.
	Circulation is reduced because of excess pressure on the sensor (e.g., between the sensor and a hard surface).	Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.
	The digit is cold.	Warm the digit by rubbing or covering with a blanket.
		Position the sensor at a different site.
	The patient module is not paired to the display.	Make sure the patient module is paired with the display.
		Verify that the Connection Status LED is green on both the display unit and the patient module.

Problem	Possible Cause	Possible Solution
Unable to obtain a green pulse display on the bargraph, cont'd.	The sensor is applied incorrectly.	Apply the sensor correctly.
	There is possible interference from one of the following sources: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate any interference. Make sure that the sensor is not placed on the same arm being used for other patient therapies or diagnostics (e.g., blood pressure cuff).
	The red LED is not illuminated in the finger insertion area.	Ensure that the sensor is securely attached to the 4100.
		Check the 4100's batteries.
		Check the sensor for any visible signs of deterioration.
		Contact your distributor or NONIN Customer Support.
Frequent or steady pulse quality indication.	There is excessive ambient light.	Shield the sensor from the light source.
	The sensor is applied to a polished or artificial fingernail.	Apply the sensor to a finger without artificial or polished nails.
		Position the sensor at a different site.
	The red LED is not illuminated in the finger insertion area.	Ensure that the sensor is securely attached to the 4100.
		Check the sensor for any visible signs of deterioration.
		Contact your distributor or NONIN Customer Support.
	Patient motion is excessive.	Reduce patient motion.

Problem	Possible Cause	Possible Solution
A dash (-) appears in the %SpO_2 display.	A poor signal from the digit is being detected.	Reposition the digit or insert a different digit and keep the sensor motionless for at least 10 seconds.
		Position the sensor at a different site.
	The digit was removed from the sensor.	Reinsert the digit and keep the sensor motionless for at least 10 seconds.
	The system is not functioning.	Turn off the unit, check all connections, and retry.
		Verify that the 4100 is paired with the display.
		Verify that the Connection Status LED is green on both the display unit and the patient module.
		Contact your distributor or NONIN Customer Support.
An error code appears in the display area.	The system encountered an error.	1. Turn the unit off and then back on again to remove the error code. 2. If the error persists, disconnect all power (AC and battery), and then reconnect the power and turn the unit back on. 3. If the error still persists, note the error code and contact your distributor or NONIN Customer Support.

Problem	Possible Cause	Possible Solution
The unit is in Alarm mode, but no audible alarms can be heard.	The 2-minute Alarm Silence button is activated.	Press the Alarm Silence button to re-engage alarm volume, or wait for two minutes—and alarm tones will automatically re-engage.
	DIP switch 2 is in the UP position, and the unit's volume is set to zero.	Adjust the alarm volume, or return DIP switch 2 to the DOWN position if you desire audible alarms.
	The system is not functioning correctly.	Contact your distributor or NONIN Customer Support.
The devices will not pair.	The sensor has not been disconnected and reconnected.	Disconnect and reconnect the sensor to the 4100.
	The patient module is out of range.	Ensure that the patient module is in range while being paired (approximately 30 feet—spherical radius).
	The Bluetooth Control button was not pressed and held while turning on the display unit.	Starting with the display unit turned off, press and hold the Bluetooth Control button while turning on the display unit. (See "Device Pairing" for more information.)

If these solutions do not correct the problem, please contact your distributor, or contact NONIN Customer Support at **(800) 356-8874** (USA and Canada) or **+1 (763) 553-9968.**